

Applicants : Adrian Gilbert et al.
U.S. Serial No.: 09/788,131
Filed : February 16, 2001
Page 2

In the Claims

Please amend the claims by replacing all prior versions, and listings, of claims pursuant to 37 C.F.R. §1.121 as modified by 68 Fed. Reg. 38611 (June 30, 2003) as follows:

Please cancel claims 55 and 67-74 without disclaimer or prejudice to applicants' rights to pursue the subject matter of these claims in this or another application.

1. (Previously Presented) A pharmaceutical composition comprising as an active ingredient a therapeutically effective amount of glatiramer acetate and an amount of microcrystalline cellulose in excess of 50 % by weight of the composition.
2. (Canceled)
3. (Original) The pharmaceutical composition of claim 1, wherein the amount of microcrystalline cellulose is at least 70 % by weight.
4. (Original) The pharmaceutical composition of claim 1, wherein the amount of microcrystalline cellulose is from about 60% to about 90% by weight.
5. (Original) The pharmaceutical composition of claim 1, wherein the amount of microcrystalline cellulose is from about 70% to about 80% by weight.
6. (Original) The pharmaceutical composition of claim 1, wherein the microcrystalline cellulose has a moisture content of up to 5.0%.

Applicants : Adrian Gilbert et al.
U.S. Serial No.: 09/788,131
Filed : February 16, 2001
Page 3

7. (Original) The pharmaceutical composition of claim 1, wherein the microcrystalline cellulose has a moisture content of up to 1.5%.
8. (Original) The pharmaceutical composition of claim 1, further comprising a disintegrant.
9. (Original) The pharmaceutical composition of claim 8, wherein the disintegrant is selected from the group consisting of kaolin, starch, powdered sugar, sodium starch glycolate, crosscarmelose sodium, carboxymethyl cellulose, microcrystalline cellulose and sodium alginate.
10. (Original) The pharmaceutical composition of claim 9, wherein the disintegrant is a pregelatinized starch.
11. (Original) The pharmaceutical composition of claim 10, wherein the starch has a moisture content of up to 14%.
12. (Original) The pharmaceutical composition of claim 10, wherein the starch has a moisture content of up to 12%.
13. (Original) The pharmaceutical composition of claim 10, wherein the starch has a moisture content of up to 7%.
14. (Original) The pharmaceutical composition of claim 10, wherein the starch has a moisture content of up to 5%.
15. (Original) The pharmaceutical composition of claim 1, further comprising a lubricant.

Applicants : Adrian Gilbert et al.
U.S. Serial No.: 09/788,131
Filed : February 16, 2001
Page 4

16. (Original) The pharmaceutical composition of claim 15, wherein the lubricant is selected from the group consisting of talc, sodium stearyl fumarate, magnesium stearate, calcium stearate, hydrogenated castor oil, hydrogenated soybean oil, and polyethylene glycol.
17. (Original) The pharmaceutical composition of claim 16, wherein the lubricant is magnesium stearate.
18. (Original) The pharmaceutical composition of claim 1, further comprising an enteric coating.
19. (Previously Presented) The pharmaceutical composition of claim 18, wherein the enteric coating is methacrylic acid copolymer.
20. (Original) The pharmaceutical composition of claim 18, wherein the enteric coating is selected from the group consisting of cellulose acetate phthalate (CAP), hydroxypropyl methyl cellulose phthalate (HPMCP), carboxymethyl ethyl cellulose (CMEC), or aminoalkylmethacrylate copolymer.
21. (Original) The pharmaceutical composition of claim 1, further comprising a film coating under the enteric coating.
22. (Original) The pharmaceutical composition of claim 21, wherein the film coating is selected from the group consisting of hydroxy propyl methyl cellulose (HPMC) and poly vinyl alcohol (PVA).
23. (Original) The pharmaceutical composition of claim 1 in

Applicants : Adrian Gilbert et al.
U.S. Serial No.: 09/788,131
Filed : February 16, 2001
Page 5

solid form.

24. (Original) The pharmaceutical composition of claim 23, wherein the solid form is selected from the group consisting of a tablet, a hard gelatin capsule, a pellet and a particulate formulation.
25. (Previously Presented) The pharmaceutical composition of claim 24, wherein the solid form is a tablet and the effective amount of glatiramer acetate is from about 0.1 mg to about 300 mg.
26. (Previously Presented) The pharmaceutical composition of claim 25, wherein the effective amount of glatiramer acetate is from about 5 mg to about 100 mg.
27. (Previously Presented) The pharmaceutical composition of claim 25, wherein the effective amount of glatiramer acetate is about 5 mg.
28. (Previously Presented) The pharmaceutical composition of claim 25, wherein the effective amount of glatiramer acetate is about 50 mg.
29. (Previously Presented) A pharmaceutical composition in solid form comprising as an active ingredient a therapeutically effective amount of glatiramer acetate 70%-80% by weight of microcrystalline cellulose, and an enteric coating.
30. (Previously Presented) The pharmaceutical composition of claim 29, wherein the effective amount of glatiramer acetate is about 5 mg.

Applicants : Adrian Gilbert et al.
U.S. Serial No.: 09/788,131
Filed : February 16, 2001
Page 6

31. (Previously Presented) The pharmaceutical composition of claim 29, wherein the effective amount of glatiramer acetate is about 50 mg.
32. (Original) The pharmaceutical composition of claim 1, further comprising a pharmaceutically acceptable carrier suitable for application to mucosal linings, so as to thereby form a composition suitable for application to the mucosal linings of a subject.
33. (Original) The pharmaceutical composition of claim 32, wherein the carrier is chitosan.
34. (Original) The pharmaceutical composition of claim 33, further comprising a pharmaceutically effective amount of an anti-microbial preservative.
35. (Original) The pharmaceutical composition of claim 34, wherein the anti-microbial preservative is selected from the group consisting of sodium benzoate, methyl paraben, benzalkonium chloride, and propyl paraben.
36. (Canceled)
37. (Original) The pharmaceutical composition of claim 32, in dry powder form.
38. (Original) The pharmaceutical composition of claim 32, wherein the mucosal linings are bronchi-associated lymphoid tissue.
39. (Original) The pharmaceutical composition of claim 32,

Applicants : Adrian Gilbert et al.
U.S. Serial No.: 09/788,131
Filed : February 16, 2001
Page 7

formulated for oral administration.

40. (Original) The pharmaceutical composition of claim 32, formulated for nasal administration.

41. (Original) The pharmaceutical composition of claim 32, formulated for pulmonary administration.

42. (Original) The pharmaceutical composition of claim 32, formulated for buccal administration.

43. (Previously Presented) A process for manufacturing the composition of claim 1, comprising:

- a) milling the glatiramer acetate
- b) dry mixing the milled glatiramer acetate with at least 50% by weight of microcrystalline cellulose.

44-49. (Canceled)

50. (Previously Presented) The pharmaceutical composition of claim 29, wherein the effective amount of glatiramer acetate is from about 5 mg to about 100 mg.

51. (Previously Presented) The pharmaceutical composition of claim 29, wherein the effective amount of glatiramer acetate is about 5 mg.

52. (Previously Presented) The pharmaceutical composition of claim 29, wherein the effective amount of glatiramer acetate is about 50 mg.

53. (Previously Presented) The pharmaceutical composition of claim 29, wherein the effective amount of glatiramer

Applicants : Adrian Gilbert et al.
U.S. Serial No.: 09/788,131
Filed : February 16, 2001
Page 8

acetate is from about 0.01 mg/kg to about 2 mg/kg.

54. (Previously Presented) The pharmaceutical composition of claim 29, wherein the effective amount of glatiramer acetate is from about 0.05 mg/kg to about 1 mg/kg.

55-60. (Canceled)

61. (Previously Presented) The pharmaceutical composition of claim 1, further comprising a protease inhibitor.

62. (Previously Presented) The pharmaceutical composition of claim 3 in solid form.

63. (Previously Presented) The pharmaceutical composition of claim 62, wherein the solid form is selected from the group consisting of a tablet, a hard gelatin capsule, a pellet and a particulate formulation.

64. (Previously Presented) The process of claim 43, further comprising applying a film coating.

65. (Previously Presented) The process of claim 43, further comprising applying an enteric coating.

66. (Previously Presented) The process of claim 65, wherein the enteric coating is applied using a rotating pan system.

67-74. (Canceled)